

Sourcing Guide

The Nevirapine Infant-Dose Pouch for Use in Prevention of Mother-to-Child Transmission of HIV/AIDS Programs

Version 1
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USAID
FROM THE AMERICAN PEOPLE

Acknowledgements and Copyright

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The NVP infant-dose pouch was developed through a public-private partnership among PATH, USAID, and Boehringer Ingelheim (manufacturer of Viramune[®] brand NVP).

PATH's initial NVP packaging feasibility work was supported through Population Services International (PSI)'s AIDSMARK project, a USAID initiative. PSI, with PATH collaboration, conducted early-stage assessments of acceptability for potential NVP packaging options in Tanzania and Zambia.

PATH collaborated with Elizabeth Glaser Pediatric AIDS Foundation, Family Health International, and the National HIV/AIDS Control Program of Kenya to pilot and introduce the NVP infant-dose pouch in Kenya.

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Introduction

Purpose

As part of a public-private partnership with the US Agency for International Development (USAID) and Boehringer Ingelheim (BI; manufacturer of Viramune^{®1} brand nevirapine), PATH developed a simple solution, the nevirapine (NVP) infant-dose pouch. This pouch can help prevention of mother-to-child transmission of HIV/AIDS (PMTCT) programs overcome the packaging challenges to increased coverage of at-risk newborns with the infant dose of NVP.

The purpose of the *Sourcing Guide* is to provide PMTCT programs with the information they would need to independently procure NVP infant-dose pouches for use in PMTCT services. While PATH developed the NVP infant-dose pouch and validated its use in the field, PATH is not a manufacturer or supplier of the pouch.

PATH's design for the pouch uses readily available packaging materials and processes which may be locally available in many countries. This guide will help programs either:

- Procure pouches from a current manufacturer(s) identified by PATH or
- Engage a local or regional packaging manufacturer to produce pouches of similar function and quality.

This guide includes the design criteria and technical specifications as well as the technical drawings that will be required by manufacturers. Potential manufacturers have been identified, and contact and quotation information is provided if it was available at the time this guide was printed.

Also included in the guide are the information and resources to support organizations considering introduction of the pouch in PMTCT programs. These include guidelines for labeling and materials to assist with training and introduction.

¹ Viramune is a registered trademark of Boehringer Ingelheim

Background

Challenges in Implementing PMTCT Programs

It is estimated that 2.2 million children under the age of 15 around the world are HIV positive (HIV+), with some 560,000 becoming newly infected in the year 2004.² Clinical trials have shown single-dose NVP to be an efficacious therapy for reducing mother-to-child transmission of HIV-1. The single-dose therapy includes a 200 mg NVP tablet (hereafter referred to as NVP tablet) to be taken by the mother at the onset of labor and a fixed-dose of 0.6 ml of NVP oral suspension (hereafter referred to as NVP syrup) for the infant dose, to be given to the baby within 72 hours of birth.^{3,4}

Provision of the NVP tablet at antenatal care (ANC) visits for women to take home in advance of labor seems to have increased in prevalence in the last few years. However, provision of the infant-dose NVP syrup in advance of giving birth has been slow to follow; the lack of single-dose packaging for NVP syrup has been a critical barrier, often preventing provision to HIV+ women at antenatal care visits.⁵ In facilities that have been providing the infant dose in advance of birth for PMTCT, clinic staff have been observed using ad hoc combinations of household tinfoil, thin plastic bags, sheet paper, and small cardboard boxes to package the NVP syrup filled syringe (see Image 1). When wrapping materials were not available, the infant dose often was not dispensed in advance of giving birth.

Improved Packaging for the Infant Dose

To provide an easy-to-use and more consistent approach for packaging and protecting an oral dosing syringe filled with a 0.6-ml infant dose of NVP syrup, PATH designed a medical-grade, self-adhesive sealing foil laminate pouch (hereafter referred to as the NVP infant-dose pouch).



Image 1. Ad hoc packaging observed in Kenya.

² UNAIDS. *AIDS Epidemic Update: December 2004*. 2004.

³ Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet*. 1999;354(9181):795–802.

⁴ Moodley D, Moodley J, Coovadia H, et al. A multicenter randomized controlled trial of nevirapine versus a combination of zidovudine and lamivudine to reduce intrapartum and early postpartum mother-to-child transmission of human immunodeficiency virus type 1. *Journal of Infectious Diseases*. 2003;187(5):725–735.

⁵ Stringer E, Sinkala M, Stringer J, et al. Prevention of mother-to-child transmission of HIV in Africa: success and challenges in scaling up a nevirapine-based program in Lusaka, Zambia. *AIDS*. 2003; 17:1377–1382.

Simple graphic instructions for home storage and administration were developed and printed on the pouch (Image 2).

The combination of NVP syrup and an oral dosing syringe that can be securely capped, and the NVP infant-dose pouch:

- Creates a single-dose packaging solution that can be implemented at the facility level without requirements for additional equipment or power resources.
- Improves ease of use for PMTCT providers and HIV+ pregnant women.
- Provides protection for the infant dose while being transported and stored by the HIV+ pregnant woman until after giving birth.
- Increases the overall quality assurance for distribution of NVP syrup to HIV+ pregnant women prior to labor/delivery by standardizing packaging practices using known and validated designs.
- Potentially increases the coverage of NVP syrup provided during ANC visits. Studies are underway to determine if sending the infant dose home in advance of giving birth increases uptake.



Image 2. NVP infant-dose pouch, Exacta-Med dispenser, and NVP bottle.

Field Validation in Kenya

In 2006, a pilot introduction was conducted to evaluate the nevirapine infant-dose pouch in 13 PMTCT facilities in Kenya. Between February and June 2006, 543 pouched doses of NVP syrup in 1-ml Exacta-Med^{®6} oral-dosing dispensers were provided to HIV+ pregnant women in advance of giving birth. More details on the Exacta-Med dispenser are included as Appendix 1.

Data on acceptability and use were collected through interviews with health workers, managers, and HIV+ women. PMTCT staff reported the pouch reduced the time required to prepare the infant dose and felt that it improved the quality of services they were providing to clients.

In September 2006, Kenya's National HIV/AIDS and STD Control Program (NAS COP) will be introducing the NVP infant-dose pouch nationally for use in facilities where PMTCT services are provided. More information on the pilot introduction of the pouch in Kenya can be found on the PATH website: www.path.org/projects/nvp_pouch_resources.php.

⁶ Exacta-Med[®] is a registered trademark of Baxa Corporation.

Specifications for the Nevirapine Infant-Dose Pouch

Design Criteria for the NVP Infant-Dose Pouch

PATH developed and followed these basic performance criteria for designing the NVP infant-dose pouch for PMTCT program use:

- Sized to enclose a 1-ml oral-dosing syringe, with a cap, prefilled with 0.6 ml of NVP syrup, with limited unused space.
- Tamper evident.
- Robust to protect prefilled oral-dosing syringe.
- Easy to use with little or no training required.
- Ability to provide pictorial instruction for low-literate users.
- Ability to label and provide expiry date and other information for the user.

If a PMTCT program decides to make modifications to the PATH pouch design, the new pouch design should be evaluated to ensure these basic criteria are met.

Technical Specifications

Technical specifications were developed for manufacturing the NVP infant-dose pouch. Included in the specifications are details of the material construction, dimensions with tolerances, printing, seal, and incorporation of tear notches. These are all listed on the next page.

Master Technical Specifications for the Nevirapine Infant-Dose Pouch

Material Construction

- Method: Lamination.

| Layer Order | Material | Thickness | Tolerances |
|----------------------|---------------------------------|-------------------|--------------|
| (1) exterior surface | polyester | 48 gauge | +/- 5 gauge |
| | adhesive | | |
| (2) sandwiched | foil | 30 gauge | +/- 3 gauge |
| | adhesive | | |
| (3) interior surface | linear low density polyethylene | 300 gauge (3 mil) | +/- 30 gauge |

Dimensions with tolerances (in inches)

- See technical drawing (next page) for complete dimensions.
- 3.0000 x 8.0000 outer dimensions plus 1.125 lip.
- 2.5000 x 8.0000 inner dimensions.
- All dimensions +/- 10%.

Printing (optional)

- Surface printed, 2 colors 1 side.
- Indexed.
- Exact artwork size may vary though at minimum to occupy 66% of the surface (1 side), up to maximum printable area of that side.

Seal

- Permanent self-adhesive with release ply.

Miscellaneous

- With tear notches.

Technical Drawing

A technical drawing was created to assist with and ensure proper manufacturing of the NVP infant-dose pouch (Image 3). As previously noted, the pouch is specifically designed to enclose a 1-ml oral-dosing syringe prefilled with 0.6 ml of NVP syrup. These measurements are detailed below. Location of the adhesive and tear notches are also included in this drawing. A larger version of this drawing is included as Appendix 2.

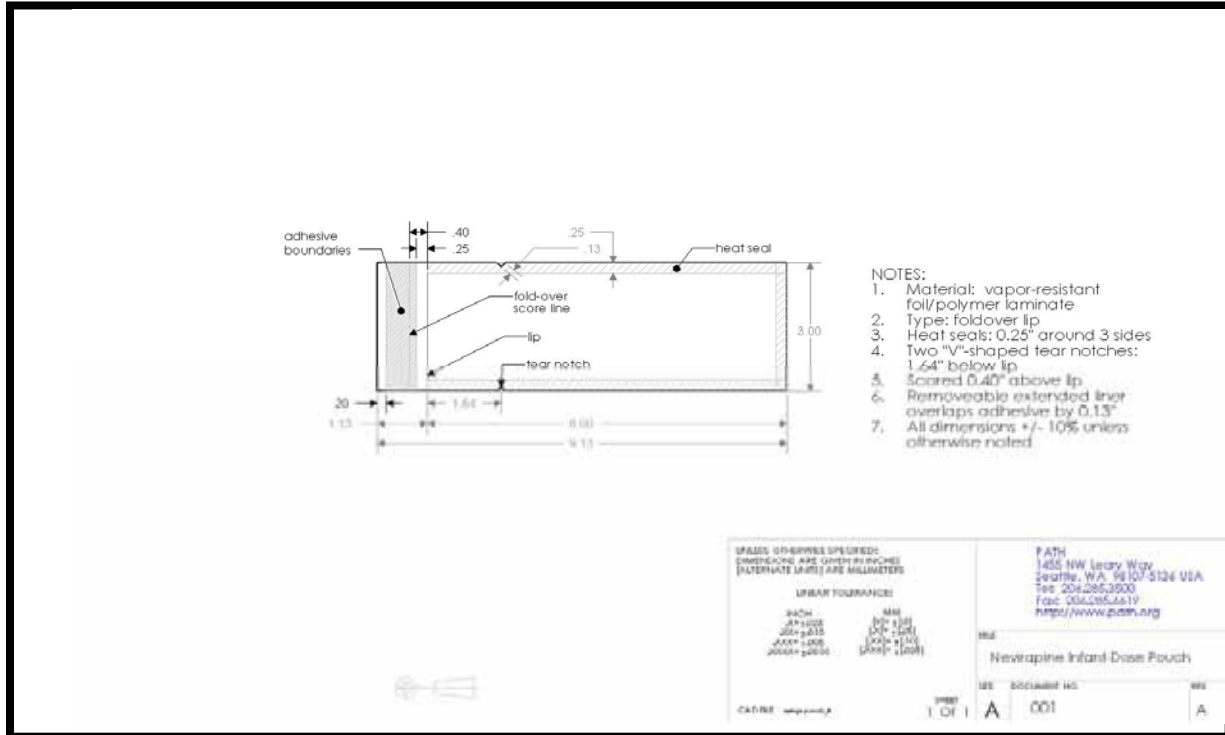


Image 3. Technical drawing of the NVP infant-dose pouch.

Pouch Sourcing

Manufacturers

PATH does not manufacture or supply the NVP infant-dose pouch. As previously noted, the purpose of this guide is to provide programs with the information needed to procure supplies for the NVP infant-dose pouch. PATH has identified a number of potential manufacturers for the NVP infant-dose pouch.

The NVP infant-dose pouch is made from a common form of flexible laminate barrier packaging, which is used in pharmaceutical, medical, food, and cosmetic industries around the world. It is likely that packaging manufacturers in many countries are capable of producing this type of pouch. Programs should consider procuring from the manufacturers listed in this guide (Appendix 3) and/or explore other packaging manufacturers, including local companies.

LPS Industries (see box on next page) is the packaging manufacturer that PATH contracted to produce prototype and field evaluation quantities of the NVP infant-dose pouch. LPS will also manufacture the 70,000 pouches being procured for Kenya's national roll out. Other manufacturers, which are listed as potential manufacturers of the NVP infant-dose pouch, have represented to PATH that they are able to provide pouches that meet PATH's Master Technical Specification (included above), although PATH has not actually procured pouches from these manufacturers. Full details for each potential manufacturer are provided with Appendix 3.

Please contact manufacturers directly to confirm product availability, obtain quotes and samples, and place orders. A sample communication requesting a quote for pouches is included as Appendix 4.

Quality Assurance

It is important to ensure that the packaging materials used in the manufacturing process are of sufficient quality. Request a sample of the pouch that will be manufactured or samples of other products made from the same materials in order to assess the quality.

LPS Industries

Contact and Quotation Information for LPS

- Location: New Jersey, USA; www.lpsind.com.
- To place an order, contact: Tom Leonard (tom.l@lpsind.com; +1-800-275-6577; +1-714-255-8123).
- Product reference: VF-42 Vapor Flex Barrier Bag.
- Product technical details: Per customer specification.
- Typical turnaround/timeframe: 6 to 8 weeks, FOB mill.
- Pricing: Contact LPS to obtain a current quote for your quantity.

| Illustrative order volumes and pricing as of July 2006. | | |
|--|---|---|
| Quantity | Price per 1,000 units, including printing (in US dollars) | Total price excluding set-up charges (in US dollars)* |
| 100,000 units | \$85 | \$8,500 |
| 50,000 units | \$89 | \$4,450 |
| 25,000 units | \$110 | \$2,750 |
| 10,000 units | \$152 | \$1,520 |
| 5,000 units | \$249 | \$1,245 |

*One time set-up charges are approximately \$350.

Details for Consideration

- Minimum order: 5,000 units.
- Shipping: When estimating shipping costs, note that 1,000 pouches weigh about 10 Lbs.
- Payment options: Credit approval or payment up front required to secure order. If credit approved, terms are net 30 days. Most forms of payment accepted.
- Printing/label artwork: Send electronic graphics files to graphicarts@lpsind.com. Acceptable graphics file formats include Adobe Illustrator (.ai) among others. Note that an order cannot be scheduled for production until LPS has received customer's final artwork. LPS will provide proofs for final approval.

Pouch Labeling

PATH has developed and validated graphics for a label that can be used with NVP infant-dose pouch. The label has a graphic focus and includes instruction for storage and administration. The label also provides a place for a provider to note the expiry information or provide additional instructions. Below are examples of the labels used in the pilot introduction of the NVP infant-dose pouch in Kenya (see Images 4 and 5). This label is currently available in English and Kiswahili for downloading from PATH's website (www.path.org/projects/nvp_pouch_resources.php). In the future, additional languages will be available.

Guidelines for Adapting the PATH-Designed Label

This label is intended for adaptation and is available as an EPS file. The file includes the five panels of graphics and language as well as the "use before" and "note" lines. Requests for this file should be sent to Adriane Berman at PATH (aberman@path.org). Programs may want to provide additional information or may need to make changes to meet a country's pharmaceutical product dispensing regulations. Organizations may also want to include logos as deemed appropriate (per the examples that follow). This label may be freely used and adapted for educational or noncommercial purposes.

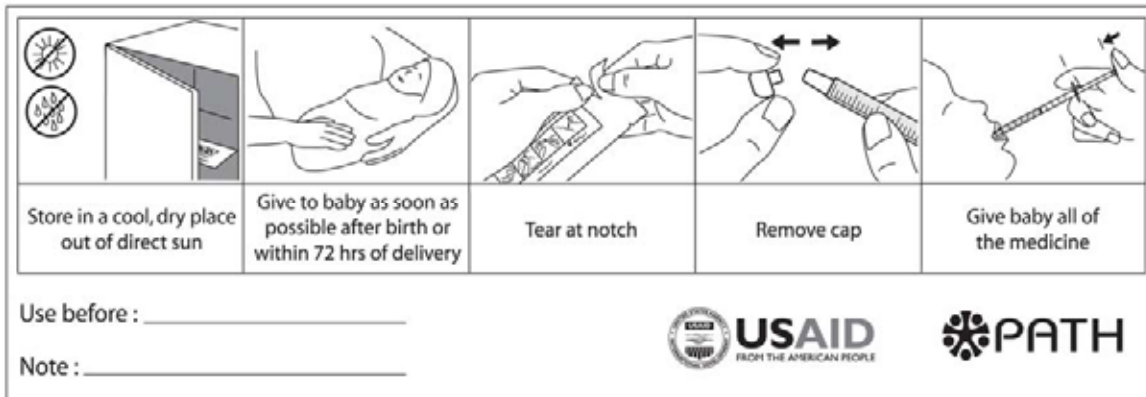


Image 4. English label for the NVP infant-dose pouch with examples of logos used.



Image 5. Kiswahili label for the NVP infant-dose pouch with examples of logos used.

Printing/Labeling Through the Pouch Manufacturers

As previously noted, the label for the NVP infant-dose pouch can be printed directly on the pouch by the manufacturer. When contacting manufacturers, check that the quotes they provide include printing costs. Also included with the manufacturer details is information regarding printing requirements. Review the requirements closely with the manufacturer and require proofs before final production.

Labeling Pouches Manually

As an alternative to purchasing preprinted pouches, you may wish to make your own labels and manually affix these to unprinted pouches. It is important to note that this is a labor-intensive process, so it is best used for making up to a few hundred pouches. Consider the cost of labor when determining whether to have labels printed on the pouches by the manufacturer. Instructions for printing and manually labeling pouches are included as Appendix 5.

Additional Considerations for Using the Nevirapine Infant-Dose Pouch

Dispensing and Labeling Regulations

It is critical to consider pharmaceutical product dispensing and labeling regulations when planning to introduce the NVP infant-dose pouch into your PMTCT program. Regulations vary by country. Review the country's guidelines for PMTCT services to ensure your program is operating within these regulations.

BI Guidelines for the Administration of Viramune®

BI, the manufacturer of Viramune® brand NVP has developed a set of guidelines for use of their product for PMTCT. These guidelines are included as Appendix 6.

PATH Introduction Tools Available for Use

PATH has developed a set of tools to help programs introduce the NVP infant-dose pouch. These tools include a training manual to guide the training of health workers on how to fill the Exacta-Med dispenser, package it in the foil pouch, and provide instructions for use to the women. A job aid has also been developed to reinforce the messages conveyed during the training (Appendix 7).



Image 4. A nurse in Kenya dispenses the NVP syrup, prefilled in an Exacta-Med® dispenser and packaged in the NVP infant-dose pouch.

PATH introduction tools are available for downloading from PATH's website: www.path.org/projects/nvp_pouch_resources.php.

Accessing the PMTCT Donations Program

The PMTCT Donations Program is a joint effort of BI and Abbott Laboratories. BI offers Viramune® at no cost to eligible countries for the PMTCT of HIV-1. Abbott donates its Determine® HIV 1/2 diagnostic tests in eligible countries for pregnant women, their spouses, and children (18 months and older) of those women who test HIV+. Baxa's Exacta-Med dispenser is also available at no cost through the Donations Program.

A list of eligible countries and instruction on how to apply to the program are available on the Donations Program's web site: <http://www.pmtctdonations.org/en/about/countries.aspx>. Donations are available to governments, nongovernmental organizations, charitable organizations, and health care providers with comprehensive PMTCT programs operating with the approval of local governments.

Demand Forecasting

As a component of the PMTCT Donations Program, Axios International developed a set of monitoring, reporting, and forecasting tools to help countries manage PMTCT supplies, including stock inventory and forecast order need. These tools are available on the Donation Program web site through the following link: <http://www.pmtctdonations.org/ftp/PMTCT-Forecasting-Tool-Axios-Feb-08-05.xls> (accessed July 2006). Use of this tool can generate data to help forecast program needs for the foil pouch. It is estimated that one 20-ml bottle of NVP covers 25 children.

abvp24531

Appendix 1. Details on the Exacta-Med Dispenser

Exacta-Med Oral Dispenser

The Exacta-Med dispenser, manufactured by Baxa, is the oral-dosing syringe that is currently available to qualifying programs at no cost through the prevention of mother-to-child transmission (PMTCT) of HIV/AIDS Donations Program.⁷ In addition, BI has documented Viramune[®] stability in this dispenser and determined that after filling the dispenser with NVP oral suspension, the contents of the dispenser should be used within two months.⁸

The design features of the Exacta-Med[®] dispenser make it an optimal oral-dosing syringe for prefilling the NVP syrup at a health facility and sending it home with an HIV+ woman. These include:

- Unique tip shape which is incompatible with hypodermic needle and luer lock hubs. This makes it difficult to attach any form of needle to the dispenser, so potential for reuse as an injection syringe is minimized.
- Internal sealing tip cap provides increased protection for handling and storage.

More information on this dispenser and ordering information is available at the Baxa website: <http://www.baxa.com>.

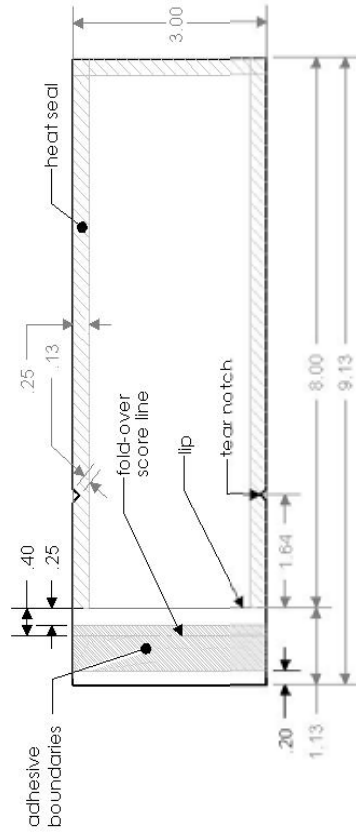
To order supplies of the Exacta-Med[®] dispenser, contact Baxa corporation:

Baxa Corporation
14445 Grasslands Drive
Englewood, CO 80112-7062
Phone: +1-303-690-4204
Toll-Free: 800-567-BAXA
Fax: +1-303-690-4804

⁷ PMTCT Donation Program website: <http://www.pmtctdonations.org/en/products/baxa.aspx> (accessed on July 17, 2006).

⁸ Guidelines for the administration of Viramune[®] 200 mg tablets and 50 mg/5 ml oral suspension for use in the prevention of mother to child transmission of HIV-1 (where single-dose prophylaxis with Viramune is indicated). Boehringer Ingelheim. 2004. <http://www.pmtctdonations.org/ftp/GuidelinesVIRAMUNE2004.pdf>.

Appendix 2. Technical Drawing of the NVP Infant-Dose Pouch



NOTES:

1. Material: vapor-resistant foil/polymer laminate
2. Type: foldover lip
3. Heat seals: 0.25" around 3 sides
4. Two "V"-shaped tear notches: 1.64" below lip
5. Scored 0.40" above lip
6. Removeable extended liner overlaps adhesive by 0.13"
7. All dimensions +/- 10% unless otherwise noted

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE GIVEN IN INCHES
(ALTERNATE UNITS) ARE MILLIMETERS

LINEAR TOLERANCE:
INCH
X = ±.028
XX = ±.010
XXX = ±.005
XXXX = ±.0010
MM
X = ±.75
XX = ±.25
XXX = ±.10
XXXX = ±.025

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TITLE

Nevirapine Infant-Dose Pouch



CAD RE $\text{width} = 0.0010$

SHEET
1 OF 1

SIZE DOCUMENT NO.

A 001

REV

A

Appendix 3. Listing of Potential Manufacturers

The following is a list of additional, potential manufacturers of the nevirapine (NVP) infant-dose pouch. PATH contacted these manufacturers and requested quotations based on the technical specifications and drawings included in this guide.

LPS Industries

Contact and Quotation Information for LPS

- Location: New Jersey, USA; www.lpsind.com.
- To place an order, contact: Tom Leonard (tom.l@lpsind.com; +1-800-275-6577; +1-714-255-8123).
- Product reference: VF-42 Vapor Flex Barrier Bag.
- Product technical details: Per customer specification.
- Typical turnaround/timeframe: 6 to 8 weeks, FOB mill.
- Pricing: Contact LPS to obtain a current quote for your quantity.

| Illustrative order volumes and pricing as of July 2006. | | |
|--|---|---|
| Quantity | Price per 1,000 units, including printing (in US dollars) | Total price excluding set-up charges* (in US dollars) |
| 100,000 units | \$85 | \$8,500 |
| 50,000 units | \$89 | \$4,450 |
| 25,000 units | \$110 | \$2,750 |
| 10,000 units | \$152 | \$1,520 |
| 5,000 units | \$249 | \$1,245 |
| *One time set-up charges are approximately \$350. | | |

Details for Consideration

- Minimum order: 5,000 units.
- Shipping: When estimating shipping costs, note that 1,000 pouches weigh about 10 Lbs.
- Payment options: Credit approval or payment up front required to secure order. If credit approved, terms are net 30 days. Most forms of payment accepted.
- Printing/label artwork: Send electronic graphics files to graphicarts@lpsind.com. Acceptable graphics file formats include Adobe Illustrator (.ai), among others. Note that an order cannot be scheduled for production until LPS has received customer's final artwork. LPS will provide proofs for final approval.

Perfecseal

About This Manufacturer

- Location: Multiple, USA and other countries; www.perfecseal.com.
- Global leader in the health care and pharmaceutical packaging market.
- Manufacturing facilities in the United States (Wisconsin, Minnesota, Indiana, and Nebraska), Malaysia, Ireland, Belgium, Brazil, and Puerto Rico.

Contact and Quotation Information for Perfecseal

- To place an order, contact: Tom Pech (trpech@bemis.com; +1-920-303-7028).
- Product reference: 35785-G.
- Product technical details: Per customer specification. Note pouch construction includes foil although polymer layers are of different type than specified (OPET/WLDPE/EVA instead of Polyester/LLDPE); manufacturer represents these differences as not significant.
- Typical turnaround/timeframe: Approximately 2 weeks.
- Pricing: Contact Perfecseal to obtain a current quote for your quantity.

| Illustrative order volumes and pricing as of July 2006 | | |
|---|--|---|
| Quantity | Price per 1,000 units including printing (in US dollars) | Total price excluding set-up charges* (in US dollars) |
| 100,000 units | \$229 | \$22,900 |
| 50,000 units | \$259 | \$12,950 |
| 25,000 units | \$301 | \$7,525 |
| 10,000 units | \$347 | \$3,470 |
| 5,000 units | \$424 | \$2,120 |
| *One time set-up charges are approximately \$1,690. | | |

Details for Consideration

- Minimum order: 5,000 units.
- Shipping: FOB Oshkosh, Wisconsin (for US orders; inquire for international orders since company has manufacturing presence in other countries). When estimating shipping costs, note that 1,000 pouches weigh about 10 lbs.
- Payment options: Credit approval or payment up front required to secure order. If credit approved, terms are 1% 10 days, net 30 days. Most forms of payment accepted.
- Printing/label artwork: Acceptable file formats include Adobe Illustrator (.ai), among others.

Tech Flex

About This Manufacturer

- Location: California, USA; www.tfpack.com.
- Converts barrier materials into different types and sizes of bags, pouches, sheets, tubing, and rolls for medical, military, food, electronics antistatic, and vacuum applications.
- Manufacturing facility at Hawthorne, California.
- Does not do printing in house; subcontracts to an outside vendor.

Contact and Quotation Information for Tech Flex

- To place an order, contact: Michael Carigan (mcarigan@tfpack.com; +1-310-962-4878).
- Product reference: Send customer specification.
- Product technical details: Per customer specification.
- Typical turnaround/timeframe: 4 weeks (2 weeks each for pouch manufacture and printing).
- Pricing: Contact Tech Flex to obtain a current quote for your quantity.

| Illustrative order volumes and pricing as of July 2006 | | |
|---|--|---|
| Quantity | Price per 1,000 units including printing (in US dollars) | Total price excluding set-up charges* (in US dollars) |
| 100,000 units | \$120 | \$12,000 |
| 50,000 units | \$150 | \$7,500 |
| 25,000 units | \$170 | \$4,250 |
| 15,000 units | \$189 | \$2,835 |
| 10,000 units | N/A | N/A |
| 5,000 units | N/A | N/A |

* One time set-up charges are approximately \$700.

Details for Consideration

- Minimum order: 15,000 units.
- Shipping: When estimating shipping costs, note that 1,000 pouches weigh about 10 lbs.
- Payment options: credit approval or payment up front required to secure order. If credit approved, terms are net 30 days. Most forms of payment accepted.
- Printing/label artwork: Acceptable file formats include Adobe Illustrator (.ai), among others.

Appendix 4. Sample Letter of Inquiry to Potential Manufacturers

Dear Mr./Ms. *(insert name)* :

My name is *(insert name)*, and I am a *(insert title)* for *(insert organization name)*, in *(insert location)*. I am looking for a manufacturer to produce a flexible laminate pouch. I have attached a drawing of the pouch for your reference and have outlined the technical specifications below.

Can you please respond and inform me if you can provide a quote for this pouch? The quantity of pouches we are interested in is *(insert quantity)*.

Master Technical Specification for the Nevirapine Infant-Dose Pouch

Material Construction

- Method: Lamination.

| Layer Order | Material | Thickness | Tolerances |
|----------------------|---------------------------------|-------------------|--------------|
| (1) exterior surface | polyester | 48 gauge | +/- 5 gauge |
| | adhesive | | |
| (2) sandwiched | foil | 30 gauge | +/- 3 gauge |
| | adhesive | | |
| (3) interior surface | linear low density polyethylene | 300 gauge (3 mil) | +/- 30 gauge |

Dimensions with tolerances (in inches)

- See technical drawing for complete dimensions.
- 3.0000 x 8.0000 outer dimensions plus 1.125 lip.
- 2.5000 x 8.0000 inner dimensions.
- All dimensions +/- 10%.

Printing (optional)

- Surface printed, 2 colors 1 side.
- Indexed.
- Exact artwork size may vary though at minimum to occupy 66% of the surface (1 side), up to maximum printable area of that side.

Seal

- Permanent self-adhesive with release ply.

Miscellaneous

- With tear notches.

Please include payment terms, and standard production lead times in your quote. We would also be interested in your international shipping experience to Africa and would like to receive samples of similar products you have produced.

Thank you for your careful review of this request, I look forward to hearing back from you.

Regards,

(insert name)

Appendix 5. Instructions for Printing and Manually Labeling Pouches

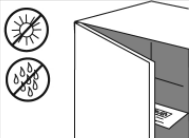


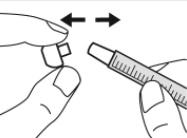

Using the Label Template Developed by PATH

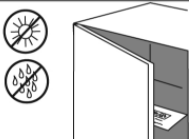


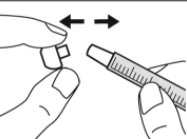

PATH has created an Adobe Acrobat PDF file template for use in printing the PATH-designed labels with a computer printer onto full sheet, 8.5-by-11-inch or A4, adhesive label stock. A copy of the English language label template is provided on the following page for reference. These English and Kiswahili templates are available for download at www.path.org/projects/nvp_pouch_resources.php. Full sheet adhesive labels are available from office supply companies. Using the templates provided, you will be able to print four labels per sheet of adhesive label stock. Use a paper cutter or scissors to separate the individual labels.

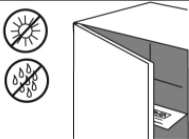

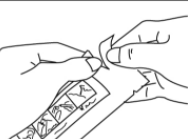
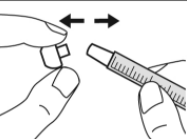
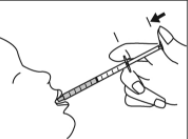
Creating and Using a Different Label Template

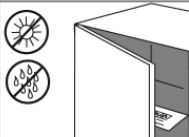


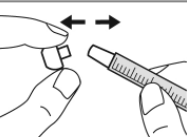

The PATH-designed label is intended for adaptation and is available as an EPS file. Requests for this file should be sent to Adriane Berman at PATH (aberman@path.org). Refer to the templates below to determine what would work best for your program's use, then create an appropriate label design template. As noted above full sheet, 8.5-by-11-inch or A4, adhesive label stock can be purchased from office supply companies. After printing labels with a computer printer, use a paper cutter or scissors to separate the individual labels.

Printing Template for the Nevirapine Infant-Dose Pouch Label (English)

| | | | | |
|---|---|---|--|---|
|  |  |  |  |  |
| Store in a cool, dry place out of direct sun | Give to baby as soon as possible after birth or within 72 hrs of delivery | Tear at notch | Remove cap | Give baby all of the medicine |
| Use before : _____ | | | | |
| Note : _____ | | | | |

| | | | | |
|---|---|---|--|---|
|  |  |  |  |  |
| Store in a cool, dry place out of direct sun | Give to baby as soon as possible after birth or within 72 hrs of delivery | Tear at notch | Remove cap | Give baby all of the medicine |
| Use before : _____ | | | | |
| Note : _____ | | | | |

| | | | | |
|---|---|---|--|---|
|  |  |  |  |  |
| Store in a cool, dry place out of direct sun | Give to baby as soon as possible after birth or within 72 hrs of delivery | Tear at notch | Remove cap | Give baby all of the medicine |
| Use before : _____ | | | | |
| Note : _____ | | | | |

| | | | | |
|---|---|---|--|---|
|  |  |  |  |  |
| Store in a cool, dry place out of direct sun | Give to baby as soon as possible after birth or within 72 hrs of delivery | Tear at notch | Remove cap | Give baby all of the medicine |
| Use before : _____ | | | | |
| Note : _____ | | | | |

August 2006



Appendix 6. Boehringer Ingelheim's Guidelines for Use of Viramune® for PMTCT

GUIDELINES FOR THE ADMINISTRATION OF VIRAMUNE® 200mg TABLETS and 50mg/5ml ORAL SUSPENSION FOR USE IN THE PREVENTION OF MOTHER TO CHILD TRANSMISSION (MTCT) OF HIV-1 (WHERE SINGLE DOSE PROPHYLAXIS WITH VIRAMUNE IS INDICATED)

The use of VIRAMUNE in programmes for the prevention of mother to child transmission of HIV should be considered, amongst other things, in the context of local health policies and 2004 WHO recommendations for the use of nevirapine, the active ingredient of VIRAMUNE.

Medication:

- Viramune® 200mg tablets
- Viramune® Oral Suspension 50 mg/5 ml (10 mg/ml):

Dosage regimen

- Tablets: 1 tablet to be administered to the mother as soon as possible after the onset of labour, preferably more than 2 hours before delivery.
- Suspension: The infant should be given a single dose of 2 mg/kg by mouth within 72 hours after birth. If possible, this dose should be given after 24 hours of birth.

In circumstances where it is not feasible to administer a dose based on weight, a fixed 0.6 ml dose can be administered as this approximates the appropriate dose to a newborn of average weight.

If the mother received her Viramune® dose less than two hours prior to delivery, then the infant should receive the single 2 mg/kg dose of Viramune® immediately after birth and a second 2 mg/kg dose within 24 – 72 hours after the first dose.

If the newborn vomits within one hour of Viramune® administration, the dose should be repeated.

Preparing the dose of suspension

Gently shake the Viramune® suspension by inverting the bottle several times. The bottle should not be shaken vigorously.

In some instances, several infants will receive medication from the same bottle of Viramune®, The suspension should be measured by pouring a small amount into a cup. The suspension should then be drawn into the oral syringe and administered orally. The remainder of the Viramune® in the cup should not be returned to the bottle and should be

discarded. **To avoid contamination of the Viramune[®] bottle, the syringe should not be placed directly into the bottle.**

Ideally, a new syringe should be used for each infant to avoid the spread of infection. The dose should be administered using a calibrated oral syringe. A hypodermic syringe may also be used for oral administration if the needle has been removed. The syringe used should be able to ensure the accurate delivery of 0,6ml of Viramune[®] suspension. If a new syringe is not available, the used syringe should be cleaned and disinfected according to local procedures prior to each use.

If requested, 1 ml syringes* will be supplied with each delivery of Viramune suspension. The syringes will accurately deliver 0,6ml of Viramune suspension and are supplied in sufficient numbers so that a new syringe can be used for each infant.

Based on results from in-use stability studies, after filling, the contents of the syringe should be used within 2 months.

Viramune[®] suspension does contain preservative to minimize the possibility of harmful microbial growth in the open bottle.

Storage of suspension

The bottle should be recapped and tightly sealed immediately following each use.

The bottle should be stored at 15°C-30°C (59°F-86°F).

The bottle should be labeled with the date on which it was opened. Based on results from in-use stability studies, after opening, the bottle should be used within 6 months.

The content of the bottle should be used in any event prior to the date of expiry printed on the label.

Bottles should be discarded after expiry.

*Syringes kindly donated by Baxa Ltd.

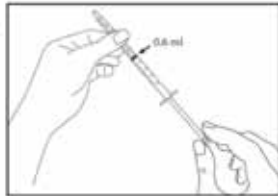
Instructions for Health Workers: Nevirapine Infant-Dose Pouch

Counsel patient on nevirapine for PMTCT:

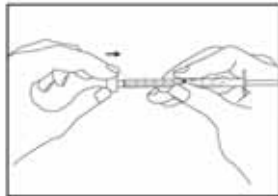
- ▶ Today you are being given nevirapine to take home.
- ▶ Nevirapine can help prevent transmission of HIV to your baby.
- ▶ Timing is important for taking the medication. If you deliver at home:
 - Tablet is for you to take when you go into labor.
 - Oral dose from the pouch should be given to the baby as soon as possible after birth or within 72 hours of delivery. (Please note to the woman that 72 hours is the equivalent of 3 days.)
- ▶ If you plan to deliver your baby at the health center, bring the tablet and the oral dose with you.

In view of the patient:

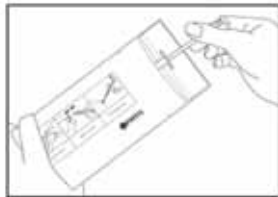
1 Fill oral dosing syringe with 0.6 ml of nevirapine oral suspension.



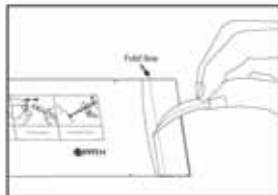
2 Place cap on tip and secure.



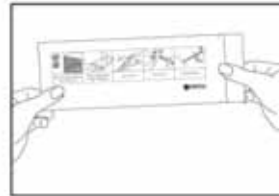
3 Place dispenser in the foil pouch.



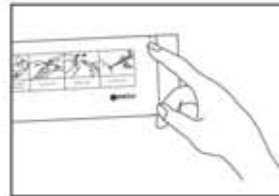
4 Remove the liner and fold the end at the fold line to seal the pouch.



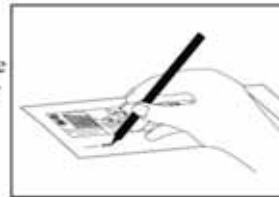
5 Review the pictorial instructions with the patient.



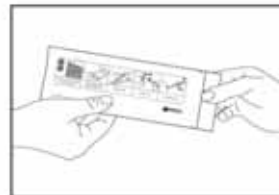
6 Show the tear point on the pouch.



7 Write the date two months from today (date dispensed) after "Use Before" and other information after "Note."



8 Give the pouch to the patient.



IMPROVED PACKAGING FOR
INFANT-DOSE NEVIRAPINE

August 2006 abhp 24308.pdf

